DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

May 31, 2016

Boston Scientific Corporation
Ms. Renuka S. Krishnan
Principal Specialist, Regulatory Affairs
3574 Ruffin Road
San Diego, CA 92123

Re: K040155
Peripheral Cutting Balloon
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II (two)
Product Code: PNO
Dated: April 28, 2004
Received: April 29, 2004

Dear Ms. Krishnan:

This letter corrects our substantially equivalent letter of July 1, 2004.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Misti L. Malone -S

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K040155

Device Name: Peripheral Cutting Balloon™

Indications For Use:

The Peripheral Cutting Balloon™ catheters are indicated for Percutaneous Transluminal Angioplasty of obstructive lesions of synthetic arteriovenous dialysis fistulae.

Prescription Use: Yes AND/OR Over-The-Counter Use: No
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K040155/S1

K040155

JUL - 1 2004

510(k) SUMMARY

Submitter's Name and Address	Boston Scientific Corporation 3574 Ruffin Road San Diego, CA 92123
Contact Person	Paul Mason, Ph.D Director, Regulatory Affairs (858)268-4488 x 2869
Common or Usual Name	PTA catheter
Product Code	LIT
Classification	Class II
Proprietary Name	Peripheral Cutting Balloon™

Predicate Devices

Boston Scientific Ultra-Thin Diamond Balloon Dilatation Catheter, K960501
Polarcath™ Peripheral Balloon Catheter system, K022061
CVSi Peripheral Balloon Catheter system, K030742

Device Description

The Peripheral Cutting Balloon (PCB) is available in nominal balloon diameters of 5.0 mm to 8.0 mm (Table 1). The device features a non-compliant balloon with four Atherotomes (microsurgical blades) mounted longitudinally on its outer surface. The proximal end of the balloon is equipped with a stainless folding spring to enhance balloon refold. The spring consists of a collar, proximal to the balloon cone; and four fingers that extend across the balloon cone and terminate before the pads that hold the atherotomes to the surface of the balloon. The catheter body has two lumens. The outer lumen is the balloon inflation lumen. The inner lumen is used to pass the catheter over a guidewire. Radiopaque markers are placed on the guidewire tubing at the ends of the atherotomes to provide visual reference points for balloon positioning within the vessel.

Table 1. Model Numbers, 1 cm PCB

Nom. Diameter	Catheter Length		
	50 cm	90 cm	135 cm
5.0 mm	BP505010	BP905010	BP1355010
5.5mm	BP505510	BP905510	BP1355510
6.0mm	BP506010	BP906010	BP1356010
7.0mm	BP505010	BP907010	BP1357010
8.0 mm	BP508010	BP908010	BP1358010

Intended Use

The Peripheral Cutting Balloon catheters are recommended for Percutaneous Transluminal Angioplasty of obstructive lesions in synthetic arteriovenous dialysis fistulae.

Substantial Equivalence

The Peripheral Cutting Balloon catheters will incorporate a substantially equivalent design, fundamental technology and intended use as those featured in predicate devices.

Performance Testing

Bench testing and biocompatibility testing were performed to support a determination of substantial equivalence. The results of these tests provide reasonable assurance that the proposed device has been designed and tested to assure conformance to the requirements for its intended use.

Clinical Experience

The 1 cm Peripheral Cutting Balloon™ was studied in a prospectively randomized clinical trial, Cutting EDGE (CUTTING Balloon HEmoDialysis Access ManaGEment Trial) that compared the Peripheral Cutting Balloon to conventional angioplasty (PTA) in the treatment of stenosed or thrombosed synthetic hemodialysis grafts. The study enrolled 340 patients, 173 in the Peripheral Cutting Balloon arm and 167 in the PTA arm at 27 centers in the US. The primary endpoint was primary patency through 6 months post-procedure. Secondary efficacy endpoints included: access circuit primary patency; procedural success; and the number of target lesion reinterventions through 6 months. Secondary endpoints also included safety: occurrence of adverse events. Adverse events were adjudicated by a CEC; a DSMB reviewed safety information throughout the enrollment portion of the study.

The Peripheral Cutting Balloon is not signficantly different from PTA with respect to the rate of target lesion primary patency through 6 months post-procedure: 47.9% $_{PCB}$ vs. 40.5% $_{PTA}$, p=0.37.

The target lesion primary patency rates for subjects with stenosed grafts were not significantly different: 51.3% $_{PCB}$ vs. 46.9% $_{PTA}$, $p = 0.84$. The national Kidney Foundation; Kidney Disease Outcome Quality Initiative for Vascular Access (KDOQI) suggests achievable primary patency rates in this group of patients to be about 50% at 6 months.

The PCB target lesion primary patency for thrombosed grafts was greater but not significant: 43.1% $_{PCB}$ vs. 32.0% $_{PTA}$, $p = 0.15$. KDOQI guidelines suggest that 40% patency is typical at 3 months; the Quality Improvement Guidelines for Percutaneous Management of the Thrombosed or Dysfunctional Dialysis Access suggest that 20% patency is typical at 6 months. The target lesion primary patency rate for subjects

treated with the Peripheral Cutting Balloon was more than double the expected rate, suggesting a clinical benefit.

Secondary efficacy endpoints did not differ significantly between treatments: procedural success, $p = 0.24$; hemodialysis access circuit patency at 6-months, $p = 0.45$; mean number of target lesion reinterventions through 6 months, $p = 0.22$. Subjects with thrombosed grafts had fewer target lesion interventions after treatment with the Peripheral Cutting Balloon; the difference between means is marginally significant: 0.7_{PCB} vs. 1.0_{PTA}, $p = 0.06$.

Device-related events, limited to dissections and perforations, were significantly more frequent in the Peripheral Cutting Balloon arm: 1.7% (3/173) dissections and 2.9% (5/173) perforations after use of the Peripheral Cutting Balloon vs. no events in the PTA arm ($p = 0.007$). When the dissection and perforation rates are considered independently, rather than pooled, the rates are not significantly different. Two of the cases (one perforation and one dissection) are protocol deviations because the Peripheral Cutting Balloon was oversized beyond the limits specified in the Directions for Use. The Quality Improvement Guidelines for Percutaneous Management of the Thrombosed or Dysfunctional Dialysis Access, updated in 2003, summarizes published complication rates. Based on the literature, the expected rate of vascular perforations or ruptures from the percutaneous management of hemodialysis is 2% to 4%. The Peripheral Cutting Balloon perforation rate of 2.9% falls within this expected range.

Only PTA balloons were used for reinterventions; 213 reinterventions were recorded during the trial. Among these reintervention procedures, there were two procedure-related vessel ruptures and two device-related perforations. Although no vessel perforations or ruptures occurred with PTA at the index procedure, these expected events did occur during reinterventions.

In summary, the Peripheral Cutting Balloon™ is not significantly different from conventional angioplasty in overall safety and effectiveness.

Conclusion

The Peripheral Cutting Balloon catheter has been shown to be Substantially Equivalent to the predicate devices.